NIH POLICY MANUAL

3006 - POLICIES AND PROCEDURES RELATING TO POSSIBLE SCIENTIFIC MISCONDUCT IN THE IRP AT NIH

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A. Purpose and Scope:

This chapter states the policies and procedures that will apply when misconduct in science is alleged or suspected in the Intramural Research Program at the NIH. The Intramural Research Program includes the NIH intramural programs, as well as the NIH-integrated intramural research programs of ADAMHA and the FDA Center for Biologics Evaluation and Research (CBER). The chapter applies to all Civil Service and Commissioned Corps employees engaged in research activities and to other scientists and trainees to the extent that they conduct research at NIH facilities under the supervision of NIH/ADAMHA/FDA employees. This guidance should be read in conjunction with the DHHS Standards of Conduct (45 CFR Part 73) and Responsibility and Procedures for Reporting Misconduct and Criminal Violations (HHS General Administration Manual (5-10)) which also apply to the Intramural Research Program at NIH. Other FDA issuances may also be applicable to FDA employees.

The chapter describes the roles and responsibilities of NIH/ADAMHA/FDA and PHS officials when misconduct in science is alleged or suspected and the procedures that will normally be followed in conducting inquiries or investigations.

B. Background:

Since the early 1980s, there has been increased concern from the public, the Congress, the Executive Branch and the scientific community regarding misconduct in science. Attention to this problem has resulted in new laws, policies and institutional arrangements to assure the integrity of the scientific process. The Public Health Service supports a major share of biomedical research in the nation and is accordingly the focal point for developing and implementing policies, procedures and institutional arrangements to support the highest standards of research conduct. On March 16, 1989, the Assistant Secretary Health published a Federal Register notice (54 FR 11080) announcing the establishment of two new offices within the Public Health Service to promote and encourage responsible conduct of science and to investigate instances of alleged or suspected misconduct within the intramural and extramural programs of the Public Health Service.

The Office of Scientific Integrity (OSI) was established in the Office of the Director,

NIH, to encourage the responsible conduct of science and to serve as the PHS focal point for implementing policies and procedures for dealing with instances of alleged or suspected misconduct. The Office of Scientific Integrity Review (OSIR) was established in the Office of the Assistant Secretary for Health to develop overall PHS policies and procedures for dealing with scientific misconduct and to provide and oversight and coordinating function on behalf of the Assistant Secretary for Health.

As a result of these institutional changes, intramural NIH policies and procedures for investigating possible scientific misconduct are being revised and updated. These procedures supersede the instructions contained in the July 7, 1986, memorandum from the Director, NIH, entitled "Policies and Procedures for Dealing with Possible Misconduct."

C. References:

1. Guidelines for the Conduct of Research in the Intramural Research Program at NIH. Available upon request from the Office of Intramural Affairs, Shannon Building (1), Room 140, 496-4920.

2. Section 493(b), Public Health Service Act (42 USC 289 b(b)) requires the Director, NIH, to establish a process for the prompt and appropriate response to information provided to the Director regarding possible scientific misconduct in connection with research for which funds have been made available under the Public Health Service Act.

3. Section 501(f), Public Health Service Act, as amended by Section 2058 (a)(2)(c) of the Anti-Drug Abuse Act of 1988 requires the Administrator, ADAMHA, to establish a process for the prompt and appropriate response to information provided to the Administrator regarding possible scientific misconduct in connection with research for which funds have been made available under title V of the Public Health Service Act.

4. HHS General Administration Manual Chapter 5-10 "Responsibility and Procedures for Reporting Misconduct and Criminal Violations."

5. PHS "Policies and Procedures for Dealing with Possible Misconduct in Extramural Research". August 31, 1990. Available upon request from the Office of Scientific Integrity, NIH, Bldg. 31, Room B1C39. (301) 496-2624.

6. PHS Grants Administration Manual Part 712 "PHS ALERT" System for Misconduct in Science."

7. NIH Manual 1130 Delegations of Authority, Program: General No. 17, Ethical Issues.

8. Privacy Act of 1974, as amended, 5 U.S.C. 552a.

9. Freedom of Information Act, 5 U.S.C. 552.

10. 45 CFR Part 5 Freedom of Information Regulations.

11. 45 CFR Part 5b Privacy Act Regulations.

D. Definitions:

1. Misconduct in Science means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error, or honest differences in interpretations or judgments of data.

2. An Inquiry consists of information-gathering and initial fact finding to determine whether an allegation or apparent instance of misconduct warrants an investigation. An inquiry is not intended to determine conclusively if wrongdoing has occurred, nor to determine guilt or innocence.

3. An Investigation is a formal examination and evaluation of all relevant facts to determine if misconduct has occurred. If misconduct is confirmed, the investigation will determine its seriousness and identify the responsible parties.

4. The PHS "ALERT" System is a procedure for collecting, controlling, and disseminating to PHS officials on a need-to-know basis information that an institution, or individual applying for or currently receiving PHS grant, cooperative agreement or contract funds for research, research training, or related activities, or being considered for appointment to a PHS advisory committee: (1) is under investigation for possible misconduct, or a decision has been made to undertake such an investigation, or (2) has been subjected to a sanction at the conclusion of an investigation for misconduct (e.g., debarment by the Secretary, DHHS, from eligibility for research funding; disqualification by the Food and Drug Administration (FDA) from use of investigational drugs; or in the case of scientists employed by the PHS, termination of employment). The information about an institution or individual is used to aid PHS officials in making informed decisions regarding PHS funds or other benefits to that institution or individual, but such information does not automatically result in a withholding of funds or other benefits. More detailed information on this system may be requested from the Director, OSI, Building 31, Room B1C-39, 496-2624.

5. The Assistant Secretary for Health (ASH) is the senior management official of the Public Health Service and the individual designated by the Secretary to make final determinations regarding scientific misconduct in the intramural programs of the Public Health Service.

6. The Office of Scientific Integrity Review (OSIR) is the PHS Office which is responsible for establishing overall PHS policies and procedures for dealing with misconduct in science, and is the PHS Office designated to oversee and review all investigative activities of PHS Agencies relating to misconduct in

science to ensure that these policies are implemented.

7. The Director of the National Institutes of Health is the senior management official of the NIH and the individual assigned by the Assistant Secretary for Health to make final Agency recommendations regarding scientific misconduct by intramural NIH researchers. The Administrator, ADAMHA, is the senior management official of ADAMHA and the individual assigned by the Assistant Secretary for Health to make final Agency recommendations regarding scientific misconduct by intramural ADAMHA researchers.

   In cases involving only intramural ADAMHA researchers, the Administrator, ADAMHA, will assume the responsibilities assigned to the Director, NIH. The Commissioner FDA, is the senior management official of FDA and the individual assigned by the Assistant Secretary for Health to make final Agency recommendations regarding scientific misconduct by intramural FDA researchers. In cases involving only intramural FDA researchers, the Commissioner, FDA, will assume the responsibilities assigned to the Director, NIH.

8. The Office of Scientific Integrity (OSI) is an NIH office with PHS-wide responsibility for overseeing the implementation of all PHS policies and procedures related to scientific misconduct, monitoring the individual investigations into alleged or suspected scientific misconduct conducted by institutions that apply for or receive PHS funds for biomedical or behavioral research projects or programs, and for conducting investigations as necessary.

9. The Deputy Director for Intramural Research (DDIR) is the senior scientific manager responsible on behalf of the Director, NIH, for oversight of the Intramural Research Program at the NIH.

10. Institutes, Centers and Divisions (ICDs) are the organizational terms encompassing all research institutes, the National Library of Medicine, and Centers and Divisions that report directly to the Director, NIH.

11. An ICD Director is the senior management official of each ICD.

12. ICD Scientific Director is the scientist responsible on behalf of the ICD Director for oversight of the ICD's intramural scientific research program. For ICDs that do not have a Scientific Director, the ICD Director will designate an individual to carry out the responsibilities specified for this official with respect to inquiries or investigations of scientific misconduct.

13. NIH Legal Advisor is the staff member of the DHHS Office of the General Counsel who has primary responsibility for providing legal advice to the Director, NIH. In cases involving only intramural ADAMHA or FDA researchers, the ADAMHA or FDA legal counsel, respectively, will carry out the responsibilities assigned to the NIH legal advisor in these policies and procedures.

E. Responsibilities:

1. The Assistant Secretary for Health (ASH) is the final deciding official in cases involving allegations or suspicions of scientific misconduct by intramural researchers at NIH. Agency findings and proposed dispositions are developed in collaboration with the OSI and are submitted to the ASH through the Office of Scientific Integrity Review. The ASH confirms or rejects the Agency findings and determines remedial actions and/or sanctions.

2. The Office of Scientific Integrity Review (OSIR) has responsibility for ensuring on behalf of the ASH that the PHS scientific misconduct effort is being performed adequately and that the investigative process is carried out in a thorough and objective manner. The OSIR reviews findings of OSI investigations and either concurs with the findings or non-concurs in the findings and requests further investigation, or OSIR may authorize closure of a case where no misconduct is found. Ultimately, the OSIR submits the case record and Agency findings to the ASH and advises the ASH on disposition of the case.

3. The Director of NIH oversees the Agency's handling of scientific misconduct issues. The Director, NIH, authorizes investigations, consults as necessary with the Director, OSI, and the Deputy Director for Intramural Research regarding the plan of investigation in particular cases, and submits the findings and decides the proposed disposition that will be recommended to the ASH.

4. Deputy Director for Intramural Research (DDRI) in consultation with the OSI conducts or arranges for the conduct of intramural NIH/ADAMHA/FDA scientific misconduct inquiries and collaborates with the Director, OSI, on all resultant investigations. The DDIR plays a central role in the development of investigation plans, monitors the progress of the investigations, and advises the Director, NIH*, regarding the findings and indicated actions.

5. Office of Scientific Integrity (OSI) is the NIH office that conducts investigations of alleged or suspected scientific misconduct in the NIH/ADAMHA/FDA intramural research program and provides expert advice to the Director, NIH*, the DDIR, and other senior management officials in matters related to possible scientific misconduct. The OSI assures that allegations or other indicator of possible misconduct are promptly and objectively reviewed. The OSI advises the DDIR when that official prepares inquiry plans.

   The OSI develops investigation plans in consultation with the DDIR. The OSI has responsibility to assure that the investigation is thorough, fair and objective. The OSI prepares recommended findings and proposed dispositions for the DDIR and the Director, NIH*. The OSI is NIH's liaison with the OSIR.

6. Institute Center and Division (ICD) Director are apprised and consulted as appropriate regarding particular inquiries and investigations. The ICD Directors

implement appropriate disciplinary or corrective actions based upon the final case disposition by the ASH.

7. Institute, Center and Division Scientific Directors (SDs) are responsible for the integrity of the intramural research program in their ICD. The SDs are apprised and consulted as appropriate in the initial inquiry when allegations or indicators of possible misconduct arise.

8. NIH Legal Advisor provides advice and assistance to the OSI, Agency or the ICD officials regarding legal issues that may arise in an inquiry or investigation.

9. Institute, Center and Division Personnel Offices provide technical guidance to the ICD Director and the OSI on procedural requirements affecting an investigation and on personnel actions necessary to resolve problems identified in an inquiry or investigation.

10. NIH/ADAMHA/FDA Employees are required to report suspected or apparent misconduct in science to the DDIR or OSI. Reports of observed or suspected misconduct may also be made to a supervisor, an ICD Scientific or Institute Director, or the DHHS Office of the Inspector General. False allegations of misconduct may do irreversible damage to the reputation of an accused scientist even when he or she is later exonerated. Therefore, an employee who intentionally makes a false misconduct allegation will be subject to disciplinary action.

F. Policies:

1. Researchers in the NIH/ADAMHA/FDA intramural program are expected to observe the highest standards of professional conduct. The norms of responsible scientific conduct should be taught in the research training process and will not be enumerated here. Guidance regarding scientific conduct may be found in Guidelines for the Conduct of Research in the Intramural Research Program at NIH.

2. All allegations or other indications that scientific misconduct may have occurred shall be promptly reviewed. All allegations that appear to have substance shall be inquired into and thoroughly investigated if warranted. Misconduct that is confirmed shall result in disciplinary actions appropriate to the specific circumstances of the case.

3. Inquiries and investigations shall be undertaken in accord with procedures that provide safeguards and confidentiality for individuals who report suspected misconduct in good faith, and for those who provide evidence. Inquiries and investigations shall be conducted in a manner that ensure fair treatment, confidentiality and due process to the subject of the inquiry/investigation.

G. Procedures:

The procedures described here are those that will normally be followed when an allegation of possible misconduct is received by an ICD or NIH/ADAMHA/FDA official. Particular circumstances in an individual case may dictate variation(s) from normal procedures but any such variation must ensure fair treatment and due process to the subject(s) of the inquiry/investigation.

1. Reports of Possible Misconduct

   An allegation or suspicion of misconduct is reported orally or in writing to a supervisor, an ICD Scientific or Institute Director, DDIR, the Office of Scientific Integrity or the DHHS Office of the Inspector General. All such reports are promptly transmitted to the OSI and the DDIR. For inquiries and investigations involving only ADAMHA or only FDA intramural researchers, the DDIR will inform the Agency Misconduct Policy Officer (MPO). For inquiries and investigations into possible misconduct in clinical studies covered by an FDA Investigational New Drug (IND) application, the DDIR will notify the FDA and MPO.

2. Inquiry Phase

   When a misconduct allegation is received, the Deputy Director for Intramural Research shall promptly determine if an inquiry is indicated. The DDIR develops an inquiry plan in consultation with the Office of Scientific Integrity, the ICD Director and the ICD Scientific Director. The OSI will advise on the inquiry strategy, the implementing plan, and on particular matters involving such questions as the evidence to be collected, individuals to be interviewed and special precautions that may be indicated. Inquiry plans will be specific to individual cases, but will in every instance provide for a thorough, fair and impartial review.

   Inquiries may be conducted by a team of scientists under the direction of the DDIR, or the DDIR may request that a senior scientist from another Institute conduct the inquiry under the direction of the DDIR. Inquiries will normally be completed within 60 working days; if necessary, extensions may be granted by the DDIR, following notification of the Director, OSI.

   The determination of whether an inquiry justifies a formal investigation will be made on a case-by-case basis, following assessment of: the accuracy and reliability of the source of information about the possible misconduct; the scope of the incident(s) and the context in which it became known; explanations and information provided by the subject(s) of the inquiry or other individuals interviewed; and any other information developed during the inquiry.

   If the inquiry fails to support the allegation of misconduct, this finding is reported to the Director, NIH*, and the OSI. The OSI may recommend additional examination before concurring or not concurring with the inquiry finding. If the DDIR and the OSI concur in a finding of no misconduct, the case

is closed and the OSI provides a case summary to the Office of Scientific Integrity Review, PHS, and the Director, NIH*. If the DDIR and the OSI disagree regarding the need for further investigation, the Director, NIH*, determines whether to continue the inquiry or close the case. If a decision is made to close the case, the OSI notifies in writing all appropriate individuals (including the source and subject(s) of the allegations) of the decision not to refer the case for investigation and the rationale for the decision. Cases involving allegations other than scientific misconduct will be referred to the Agency or Office responsible for the matter.

3. Investigation Phase

When a formal investigation is authorized, the OSI develops an investigation plan in consultation with the DDIR, the NIH Legal Advisor and other offices (e.g. ICD, personnel, etc) as needed. The Director, NIH*, authorizes an investigation in accordance with the approved plan. The OSI apprises in writing the OSIR, the senior ICD officials, and the subject scientist(s) that an investigation will be undertaken. OSI staff will advise the scientist(s) under investigation of the procedures to be followed and of his/her specific rights and opportunities to present and/or refute evidence, as detailed in the PHS "Policies and Procedures for Dealing with Possible Misconduct in Extramural Research".

Following authorization of an investigation, the OSI will conduct the investigation. Normally, the OSI will appoint an advisory panel of expert consultants to assist with the investigation. The OSI will report to the Director, NIH*, and the DDIR on the progress of the investigation. If the Director, NIH*, is not satisfied with progress in an investigation, he/she may direct a change in the plan of investigation.

Normally, an investigation should be completed within 120 working days; if necessary, extensions may be granted by the Director, OSI. When the investigation is complete, the OSI presents its findings and recommendations to the DDIR and the Director, NIH*. If there is a finding of no misconduct, the OSI recommends through the Director, NIH*, to the OSIR that the case be closed. If there is a finding of misconduct, the Director, NIH*, will recommend remedial actions and/or sanctions to the ASH. The procedures for conducting an investigation by the OSI and reporting its findings will be those established in the PHS "Policies and Procedures for Dealing with Possible Misconduct in Extramural Research."

Prior to completion of an investigation, the DDIR may recommend that interim administrative actions be taken to protect the welfare of human or animal subjects of research, prevent inappropriate use of federal funds, or otherwise protect the public interest and safety. This recommendation shall be made only after consultation with the OSI. Any interim restriction should be taken with a view toward protecting the rights of all involved parties and minimizing disruption to the project, and to the activities of those involved in the project.

All interim administrative actions must be promptly recorded in the investigative files of the OSI.

Upon completion of an investigation, the OSI investigative team, after receiving comments on a "draft report" and proposed sanctions, as appropriate, from the complainant and respondent(s), shall prepare a final written report summarizing its findings. This report shall be provided to the DDIR and the Director, NIH*. The report, with essential documentation to support the findings and any OSI recommendations for disposition of the case, will then be forwarded to the OSIR by the Director, NIH*.

4. PHS Review

   The OSIR reviews the investigative findings and recommendations regarding each case, as described in the PHS "Policies and Procedures for Dealing with Possible Misconduct in Extramural Research."

   When OSIR determines that an investigation record is fair, thorough and objective, OSIR advises the ASH regarding findings and options.

   Upon receiving the investigation findings and recommendations of NIH/ADAMHA/FDA and the findings and recommendations of the Agency and OSIR, the ASH may elect to:

   a) direct further investigation

   b) make a finding of no misconduct

   c) make a finding of misconduct and direct the imposition of remedial action. If disciplinary action for a PHS officer or employee appears warranted, the ASH may forward the findings and recommendations to the appropriate official with delegated authority to initiate disciplinary action, without a recommendation.

5. Implementation of ASH Decision

   An investigation is not considered closed until concurrence with the OSI recommendations has been obtained from the OSIR, final decisions have been made by the ASH regarding sanctions (if any), and the subject(s) of the investigation and cognizant institutional officials have been notified in writing about the outcome of the investigation. Notification shall be made by the Director, OSI.

   When an investigation confirms an instance of misconduct, the following procedures shall apply:

   (a) When the ASH has taken final action on the investigation, the OSI will notify in writing the subject(s) of the investigation, his/her

immediate supervisor and appropriate institutional official(s) of the disposition of the case. The notification shall include the final report and decision memorandum prepared by OSI, the decision memorandum prepared by OSIR, and the sanctions imposed by the ASH. If a debarment is involved, the notification shall explain the debarment process.

(b) The OSI shall ensure that PHS ALERT system file(s) on the case are updated for the duration of any approved sanctions.

(c) The OSI shall prepare a notice that identifies publications found in the investigation to require correction or retraction for publication in the Federal Register and the NIH Guide for Grants and Contracts.

(d) Except in extraordinary instances or when contrary to the Privacy Act or other law, the OSI shall prepare for publication in the Federal Register a notice about the misconduct findings, including information on the individual(s) found to have engaged in misconduct, the nature of the misconduct, and the PHS sanctions imposed. Such publication will be carried out only after a case is closed, and after completion of any disciplinary and/or debarment proceedings.

The procedures for determining sanctions will be those established in the PHS "Policies and Procedures for Dealing with Possible Misconduct in Extramural Research."

When an investigation fails to confirm an instance of misconduct, the following procedures shall apply:

(a) After concurrence from the OSIR has been received, the OSI shall notify in writing the subject(s) of the investigation, and appropriate institutional official(s).

The notification shall include the OSI report of the investigation and the decision memorandum prepared by OSI for the OSIR concurrence.

(b) The DDIR shall terminate any existing interim administrative actions.

(c) The OSI shall ensure that any files created on the case are removed from the PHS ALERT System.

(d) The OSI may prepare a notice on the findings and final disposition of the case for publication in the Federal Register if the subject(s) desires such action.

(e) The OSIR shall prepare a case summary for the ASH.

(f) The NIH/ADAMHA/FDA will take all reasonable steps to help the subject of the investigation undo damage to his or her reputation arising out of the investigative process.

H. Notification, Records, Confidentiality, Protection of Complainants:

1. Notification

   Individuals under inquiry or investigation will be notified of that fact as soon as an inquiry or investigation is authorized. Exceptions will be made if the OSI or a law enforcement official determines that prior notification is likely to interfere with the collection of evidence. Notification will include information regarding the nature of the allegations or concerns and the focus of the investigation. The individual under investigation will be informed of the procedures for comment and rebuttal and the opportunity to provide other relevant information.

2. Records of Inquiries and Investigations

   Records developed in the course of an inquiry or/and investigation will become part of a Privacy Act system of records entitled 09-37-0021, "Public Health Service Records Related to Inquiries and Investigations of Scientific Misconduct". These records will be made available only to individuals involved in or associated with an investigation, and to NIH and other PHS reviewing officials on a need-to-know basis. When appropriate, the evidence will also be made available to ICD supervisors who have direct responsibility for the research project in which the misconduct is said to have occurred.

   Any evidence suggesting criminal conduct will be referred immediately to the Office of the Inspector General, DHHS.

3. Confidentiality

   In responding to outside requests for information about ongoing investigations, NIH/ADAMHA/FDA, OSI and PHS staff shall maintain the confidentiality of such information to the greatest extent possible under the provisions of the Freedom of Information Act and the Privacy Act. Breaking confidentiality is a serious offense and will result in disciplinary action. When an inquiry/investigation is closed, the procedures for record handling will be those established in the PHS "Policies and Procedures for Dealing with Possible Misconduct in Extramural Research".

4. Protection of Complainants

   The OSI will monitor the treatment of individuals who bring allegations of misconduct or provide evidence in inquiries and/or investigations. If the

complainant requests anonymity, the OSI/DDIR will make every effort to honor that request. Instances of obvious or apparent retaliation will be reported to the ICD Director and the Director, NIH*.

I. Additional Information:

For more information on this chapter contact the Office of Intramural Affairs on 496-4920.

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